



To:

بتقدم بثقة
Moving Forward
with Confidence

رؤية عمان
2040
Oman Vision

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 110 dated 29/5/23 Regarding NCMDR Field Corrective Action of AMSCO 600 EMEA Sterilizer from (mfr: STERIS Corporation).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information





Circular No. 110/2023

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29 -05-2023

Field Safety Corrective Action of AMSCO 600 EMEA Sterilizer from STERIS Corporation.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19521
Product	AMSCO 600 EMEA Sterilizer.
Description	Steam sterilizer system.
Manufacturer	STERIS Corporation.
Local agent	Perfect Business.
The affected products	AMSCO 600 EMEA Sterilizers distributed between December 18, 2018 – December 8, 2022.
Reason	AMSCO 600 EMEA Sterilizer's chamber door may drop suddenly (free fall) while service is being performed. AMSCO 600 EMEA Sterilizer's chamber door may drop suddenly (free fall) while service is being performed.
Action	1. All affected Customers will be contacted by a STERIS Service Technician to arrange an onsite inspection of their unit(s) to perform the correction. Customers will also be provided a revised maintenance manual at no charge. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

